In the claims:

Please cancel claims 1 and 20-31 without prejudice or disclaimer.

Please add the following new claims 32-80:

32. (New) A method of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2, the method comprising:

administering to the cells a substance that inhibits the expression of 20P1F12/TMPRSS2, or expression of a molecule that is modulated by 20P1F12/TMPRSS2, whereby the status of a cell that expresses 20P1F12/TMPRSS2 is modulated.

33. (New) A method of claim 32 of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2 in a mammal, wherein the administering step comprises:

administering to said mammal a 20P1F12/TMPRSS2-related protein.

34. (New) A method of claim 32 of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2, wherein the administering step comprises:

administering to said cells an antibody or fragment thereof that specifically binds to a 20P1F12/TMPRSS2-related protein.

35. (New) A method of claim 32 of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2, wherein the administering step comprises:

administering to said cells a recombinant antibody or fragment thereof that immunospecifically binds to a 20P1F12/TMPRSS2-related protein.

36. (New) A method of claim 32 of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2 in a mammal, wherein the administering step comprises:

administering to said mammal a vector that comprises a polynucleotide comprising a 20P1F12/TMPRSS2-related protein coding sequence.

37. (New) A method of claim 32 of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2 in a mammal:

wherein the administering step comprises administering to said mammal an antisense polynucleotide complementary to a polynucleotide having a 20P1F12/TMPRSS2 coding sequence.

38. (New) A method of claim 32 of inhibiting growth of cancer cells that express 20P1F12/TMPRSS2 in a mammal:

wherein the administering step comprises administering to said mammal a ribozyme that cleaves a polynucleotide having a 20P1F12/TMPRSS2 coding sequence.

39. (New) A method of claim 33 in a human of inhibiting growth of tumor cells that express 20P1F12/TMPRSS2 and a particular HLA molecule:

wherein the administering step comprises administering to the human at least one cytotoxic T lymphocyte (CTL) epitope of 20P1F12/TMPRSS2, whereby the CTLs of the human provide an anti-tumor response.

40. (New) A method of claim 33 in a patient of inhibiting growth of tumor cells that express 20P1F12/TMPRSS2 in a mammal:

wherein the administering step comprises administering to the mammal at least one antibody epitope of 20P1F12/TMPRSS2, whereby the patient generates antibodies that have an anti-tumor response.

41. (New) A method for modulating the status of cancer cells in a mammal, wherein the cancer cells express 20P1F12/TMPRSS2, the method comprising:

administering to the mammal a substance that modulates the status of 20P1F12/TMPRSS2, or a molecule that is modulated by 20P1F12/TMPRSS2, whereby the status of a cell that expresses 20P1F12/TMPRSS2 is modulated.

42. (New) The method of claim 41, wherein the administering step further comprises administering a pharmaceutically acceptable carrier.

43. (New) The method of claim 41, wherein the administering step further comprises administering the composition in a human patient dose.

44. (New) A method of claim 41, wherein the administering step further comprises administering to said mammal a 20P1F12/TMPRSS2-related protein.

45. (New) The method of claim 44 wherein the administering step further comprises administering antigen presenting cells.

46. (New) The method of claim 44 wherein the administering step further comprises administering a CTL polypeptide epitope from 20P1F12/TMPRSS2.

47. (New) The method of claim 44 wherein the administering step further comprises administering an antibody epitope from 20P1F12/TMPRSS2.

48. (New) A method of claim 41 wherein the administering step comprises:

administering to said mammal an antibody or fragment thereof that specifically binds to a 20P1F12/TMPRSS2-related protein.

49. (New) The method of claim 48 wherein the administering step comprises administering a monoclonal antibody, or fragment thereof.

50. (New) The method of claim 48 wherein the administering step comprises administering a recombinant protein comprising the antigen-binding region of a monoclonal antibody that specifically binds to a 20P1F12/TMPRSS2-related protein.

51. (New) The method of claim 48 wherein the administering step comprises administering the antibody, or fragment thereof, labeled with a detectable marker.

52. (New) The method of claim 48 wherein the administering step further comprises administering the antibody, or fragment thereof, conjugated with a cytotoxic agent.

53. (New) The method of claim 48 wherein the mammal is a human and the administering step comprises administering a human antibody.

54. (New) The method of claim 48 wherein the mammal is a human and the administering step comprises administering a recombinant protein which comprises a chimeric or humanized antibody that binds to a 20P1F12/TMPRSS2-related protein.

55. (New) The method of claim 48 wherein the administering step comprises administering a recombinant polynucleotide that encodes the antibody or fragment thereof.

56. (New) A method of claim 41 wherein the administering step comprises administering to said mammal a vector that comprises a polynucleotide comprising a 20P1F12/TMPRSS2-related protein coding sequence.

57. (New) A method of claim 41 wherein the administering step comprises administering to said mammal an antisense polynucleotide complementary to a polynucleotide having a 20P1F12/TMPRSS2 coding sequence.

58. (New) A method of claim 56, wherein the administering step comprises administering to said mammal a vector that comprises a polynucleotide from position number 114 through number 1589 of Figure 1 (positions 112-1587 of SEQ ID NO.: 2).

59. (New) A method of claim 56, wherein the administering step comprises administering to said mammal a vector that comprises a polynucleotide that is fully

complementary to a polynucleotide from position number 114 through number 1589 of Figure 1 (positions 112-1587 of SEQ ID NO.: 2).

60. (New) A method of claim 56, wherein the administering step comprises administering to said mammal a vector that comprises a polynucleotide from position number 114 through number 1589 of Figure 1 (positions 112-1587 of SEQ ID NO.: 2) wherein T is substituted with U.

61. (New) A method of claim 56, wherein the administering step comprises administering to said mammal a vector that comprises a polynucleotide that is fully complementary to a polynucleotide from position number 114 through number 1589 of Figure 1 (positions 112-1587 of SEQ ID NO.: 2) wherein T is substituted with U.

62. (New) A method of claim 56, wherein the administering step comprises administering to said mammal a polynucleotide that hybridizes under stringent conditions to a polynucleotide of Figure 1 (SEQ ID NO.: 1) that encodes a 20P1F12/TMPRSS2 protein of Figure 1 (SEQ ID NO.: 2).

63. (New) A method of claim 41 wherein the administering step comprises administering to said mammal a ribozyme that hybridizes under stringent conditions to the 20P1F12/TMPRSS2 coding sequence.

64. (New) A method of inducing an immune response directed to 20P1F12/TMPRSS2 in a mammal, the method comprising:

exposing cells of the mammal's immune system to an immunogenic portion of a 20P1F12/TMPRSS2-related protein, whereby an immune response is induced to 20P1F12/TMPRSS2.

65. (New) A method of inducing an immune response of claim 64, said method comprising:

providing a 20P1F12/TMPRSS2-related protein that comprises at least one T cell epitope or at least one antibody epitope;

contacting the epitope with a mammalian immune system T cell or cell capable of producing antibodies, respectively, whereby the T cell is stimulated or antibodies are produced.

66. (New) The method of claim 65, wherein the immune system cell is a cell capable of producing antibodies, whereby the cell produces antibodies that specifically bind to the 20P1F12/TMPRSS2-related protein.

67. (New) The method of claim 65, wherein the immune system cell is a cytotoxic T lymphocyte (CTL), whereby the CTL is stimulated.

68. (New) A method of inducing an immune response of claim 64, the method comprising:

providing a polynucleotide that encodes an immunogenic portion of a 20P1F12/TMPRSS2-related protein;

expressing the immunogenic protein portion;

exposing cells of the mammal's immune system to the immunogenic protein portion, whereby an immune response is induced to 20P1F12/TMPRSS2.

69. (New) A method of inducing an immune response of claim 68, said method comprising:

providing a polynucleotide that encodes a 20P1F12/TMPRSS2-related protein that comprises at least one T cell epitope or at least one antibody epitope;

expressing the at least one T cell epitope or at least one antibody epitope; and,

contacting the at least one epitope with a mammalian immune system T cell or cell capable of producing an antibody, respectively, whereby the T cell is stimulated or antibodies are produced.

70. (New) The method of claim 69, wherein the immune system cell is a cell capable of producing antibodies, whereby the cell capable of producing antibodies produces antibodies that specifically bind to the 20P1F12/TMPRSS2-related protein.

71. (New) The method of claim 69, wherein the immune system cell is a cytotoxic T lymphocyte (CTL), whereby the CTL is stimulated.

Support for the new claims is found throughout the specification. Specifically, new claim 32 is supported at, *inter alia*, page 11, line 35 to page 12, line 3. New claim 33 is supported at, *inter alia*, page 13, lines 9 to 12. New claim 34 is supported at, *inter alia*, page 15, lines 20-23. New claim 35 is supported at, *inter alia*, page 16, lines 33-36. New claim 36 is supported at, *inter alia*, page 14, lines 1-9. New claim 37 is supported at, *inter alia*, page 11, lines 12 to 17. New claim 38 is supported at, *inter alia*, page 11, lines 9 to 11. New claim 39 is supported at, *inter alia*, page 22, lines 16-21 New claim 40 is supported at, *inter alia*, page 14, lines 5-9 and page 19, lines 19-21. New claim 41 is supported at, *inter alia*, page ~~11, line~~ 35 to page 12, line 3; page 15, lines 20-23; and page 18, lines 4-14. New claim 42 is supported at, *inter alia*, page 20, lines 29-36. New claim 43 is supported at, *inter alia*, page 21, lines 12-35. New claim 44 is supported at, *inter alia*, page 21, line37 to page 22, line 4. New claim 45 is supported at, *inter alia*, page 22, line 23 to page 23, line 2. New claim 46 is supported at, *inter alia*, page 22, lines 16-21. New claim 47 is supported at, *inter alia*, page 14, lines 5-9 and page 19, lines 19-21. New claim 48 is supported at, *inter alia*, page 4, lines 35 to 39, and page 18, lines 27-29. New claim 49 is supported at, *inter alia*, page 19, lines 19-21. New claim 50 is supported at, *inter alia*, page 4, lines 35 to 39 and page 14, lines 18 to 21. New claim 51 is supported at, *inter alia*, page 4, lines 35-38. New claim 52 is supported at, *inter alia*, page 20, lines 25-27. New claim 53 is supported at, *inter alia*, page 20, lines 12-15. New claim 54 is supported at, *inter alia*, page 4, lines 35-38, and page 20, lines 8-15. New claim 55 is supported at, *inter alia*, page 16, lines 33-34. New claim 56 is supported at, *inter alia*, page 23, lines 17-20. New claim 57 is supported at, *inter alia*, page 11, lines 12 to 17. New claim 58 is supported at, *inter alia*, page 10, lines 31-34, and Figure 1. New claim 59 is supported at, *inter alia*, page 10, lines 31-34, and

Figure 1. New claim 60 is supported at, *inter alia*, page 10, lines 31-34, Figure 1, and originally-filed claim 2. New claim 61 is supported at, *inter alia*, page 10, lines 31-34, Figure 1, and originally-filed claim 2. New claim 62 is supported at, *inter alia*, page 11, lines 4-7. New claim 63 is supported at, *inter alia*, page 11, lines 9 to 17. New claim 64 is supported at, *inter alia*, page 23, lines 17-26. New claim 65 is supported at, *inter alia*, page 22, lines 16-21; page 14, lines 25-32; and page 33, lines 5-14. New claim 66 is supported at, *inter alia*, page 33, lines 5-14. New claim 67 is supported at, *inter alia*, page 22, lines 16-21. New claim 68 is supported at, *inter alia*, page 23, lines 14-26. New claim 69 is supported at, *inter alia*, page 22, lines 16-21; page 14, lines 25-32; page 33, lines 5-14; and page 23, lines 14-26. New claim 70 is supported at, *inter alia*, page 33, lines 5-14. New claim 71 is supported at, *inter alia*, page 22, lines 16-21.

Applicants have not added new matter by these amendments.

COMMENTS

This Request for Continued Examination is in response to the Final Office Action mailed May 23, 2001 (Paper No. 22). With the entry of the amendments above, previously pending claims 1 and 20-31 have been cancelled, and claims 32-71 are currently pending in this application.

The Applicants thank the Examiner for the withdrawal of the objections recited in Paper No. 10, page 3, and suspension of the objection recited in Paper No. 10, page 4, pending indication of allowable subject matter.

Rejections Maintained

Previously pending claims 1 and 20-31 were rejected under 35 U.S.C. § 101 as lacking a specific asserted utility or a well established utility. The previously pending claims were also rejected under 35 U.S.C. § 112, first paragraph, for the same reasons.

Previously pending claims 1 and 20-31 are now cancelled and replaced by claims 32-71. These claims are directed to methods of inhibiting growth of cancer cells expressing 20P1F12/TMPRSS2, methods of modulating the status of cancer cells in a mammal wherein the cancer cells express 20P1F12/TMPRSS2, and methods of inducing an immune response directed to 20P1F12/TMPRSS2 in a mammal. It should be noted that Applicants do not agree with the

rejection of the previously pending claims, but as those claims are no longer pending, the arguments below are directed to the currently pending claims.

It is submitted that the new claims obviate any rejection based on lack of utility. Prostate tissue expresses 20P1F12/TMPRSS2. Once cancer of the prostate is suspected or confirmed (by any method), an immune response can be directed against 20P1F12/TMPRSS2-bearing cells. Even if 20P1F12/TMPRSS2 is expressed on both normal and cancerous tissue, since the prostate is not vital to sustain life, the entire organ can be destroyed to eliminate the cancer. Utility is thus clearly established for the methods as currently claimed, and withdrawal of the rejections is respectfully requested.

Previously pending claims 20-31 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising SEQ ID NO. 2, does not reasonably provide enablement for polypeptides comprising a fragment of the 20P1F12/TMPRSS2 protein.

Applicants do not concur with this rejection. The rejection, however, is moot, as it does not apply to the newly pending claims, and hence withdrawal of this rejection is respectfully requested.

Claims 1 and 20-31 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Wong et al. (U.S. Patent No. 6,166,194).

Applicants do not concur with this rejection. The currently pending claims in the case render the rejection moot, however. The claims of the instant application are directed to methods of inhibiting growth of cancer cells expressing 20P1F12/TMPRSS2, methods of modulating the status of cancer cells in a mammal wherein the cancer cells express 20P1F12/TMPRSS2, and methods of inducing an immune response directed to 20P1F12/TMPRSS2 in a mammal. These methods are distinct from the applications discussed in the Wong patent (gene therapy, protein replacement therapy). Thus the Wong reference does not apply to the currently pending claims, and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants submit that all issues raised in the last Office Action (rejection under 35 U.S.C. § 101, rejections under 35 U.S.C. § 112, first paragraph, and rejection under 35 U.S.C. § 102(e)) have been addressed in this response. Consideration of the newly submitted claims and early allowance is earnestly solicited.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 511582000800. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: October 23, 2001
By:

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